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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/628,933 | 07/29/2003 | Anandan Palani | IN01481KC | 7512 |

24265 7590 10/06/2006

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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| EXAMINER |
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CHANG, CELIA C

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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,933

Applicant(s)

PALANI ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants have filed an after final amendment dated Sept. 15, 2006.

In view of the following new grounds of rejections, the finality of the office action dated April 17, 2006 has been withdrawn. The after final amendment and arguments are considered a response to the now non-final action of April 17, 2006.

The amendment and response filed on Sept. 15, 2006 have been entered and considered carefully.

Claims 31-40 have been canceled. Claims 21-30 are pending.

2. Claims 21, 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

In claim 21, the terms "alkylketone" "arylketone" are improper for defining moieties because moieties must have at least one valence. "alkylketone" or "arylketone" are compounds which are absent of bonding/valence definition. Appropriate terms such as alkylcarbonyl or arylcarbonyl should be considered. Proper antecedent basis for such terms must be found in the specification.

In claims 25-28, it is self conflicting to claim a "pharmaceutical" composition without a dosage limitation i.e. effective amount because a pharmaceutical composition by definition cannot be either ineffective or toxic.

3. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 21 includes the scope of “solvate” of a compound of formula I. Solvates were defined on page 10 lines 22-24 being “.....for example, a hydrate”. It is well recognized in the chemical art that hydrate is not a variation of a compound of formula I but each hydrate is a **different** entity that commands separate molecular formula. For hydrates/solvates to be inclusive in the claims, one must be in possession of such compounds, how it was made and with what solvents. Absent of any hydrates/solvates being enabled in the specification, the specification provided no guidance or how to make such product.

4. Claims 21-30 reading on R^1 is MR^4 , wherein M is phenyl, R^4 is $C_{1-6}Alkyl-NR^{21}SO_2R^{22}$, R^2 is non-heterocyclic, R^3 is substituted or unsubstituted pyrimidine are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 10/979,075, see especially corresponding species of claim 17, 1st and 6th compound on page 70, in view of Rubini et al.

Determination of the scope and content of the prior art (MPEP §2141.01)

The copending claims are drawn to analogous compounds of the instantly “elected” scope of R^4 is $C_{1-6}Alkyl-NR^{21}SO_2R^{22}$.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant elected scope and the copending species is that instead of R^4 is $C_{1-6}Alkyl-NR^{21}SO_2R^{22}$, the copending claims are drawn to compounds wherein an ethylene chain of the $C_{1-6}Alkyl$ linker of the R^4 is replaced by an amide bond. The ethylene linker and an amide bond are considered amide bond surrogate units (see Rubini et al. whole article, especially page 6039, 9th line from bottom).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in possession of the copending claims would be motivated to replace the amide bond of the linkage with an amide bond surrogate i.e. an ethylene chain which would be the instant claims. The modification of two sets of compounds with conventional skill in biological active compounds with amide bond surrogate is prima facie obvious because one would expect such modification to produce more compounds with analogous activity.

It is not entire clear what was the basis for applicants’ argument. If applicants are arguing that no explicit language was found in Rubini as to suggest modification of the instant claimed compounds. Please note that bioisosterism is a “rational approach to drug design” (see

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Patini attached). One having ordinary skill in the art is well aware of such drug design tool as to be motivated to employ bioisosterism in modification of lead compound. It has been clearly set forth by the court that motivation is not limited to explicit language but can be either by express suggestion, or knowledge of those skilled in the art that certain references or disclosures in the references are known to be of special interest or importance in the particular field, or it may come from the nature of a problem to be solved leading inventors to look to references relating to possible solutions to that problem. *Pro-Mold and tool co. v. Great lakes plastics*, 37 USPQ2d 1626. The use of amide bond surrogate in drug design is such a well recognized modification, one having ordinary skill in the art would be in possession of the technical knowledge, the reasonable expectation of success and the choices of isosteric modifications given the Rubini disclosure. Although Rubini used peptide compounds as a model, the bioisosteric replacement is "structural" based on conformational/configurational replaceable units. Such atomic geometric configuration does not change even if the final product is not a peptide.

If applicants are arguing that the examples or species claims of the instant application having the alkyl moiety in the R4 variable being a two carbon unit while the copending claims are -CH₂-CONH-CH₂- therefore requires at least a four carbon unit as a bioisosteric replacement linker, then, applicants' attention is drawn to that the instant amended claim 21, for R4, the alkyl unit is a C1-C6 linker, thus, includes the copending bioisosteric replacement linker of four carbon unit. If applicants' argument is drawn to that all example of the instant application are drawn to the C2 linker and therefore is a teaching away from the four carbon replacement linker, then, such argument has not been incorporated into the claims as well as finding antecedent basis in the specification.

Mere argument absent of competent factual evidence provides little weight in obviating prima facie obviousness. *CFMT Inc. v. Yieldup Int. Corp.* 68 USPQ2d 1940, *In re Lindner* 173 USPQ 356.

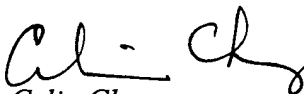
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 2, 2006


Celia Chang
Primary Examiner
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